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# मानक

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IS 14420 (1996): Tracheal Tubes for Large Animals Used for Veterinary Anaesthesia [MHD 17: Health Informatics]



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भारतीय मानक  
बड़े पशुओं की असंवेदना के लिए  
प्रयुक्त श्वासनाल — विशिष्टि

*Indian Standard*

TRACHEAL TUBES FOR LARGE ANIMALS  
USED FOR VETERINARY ANAESTHESIA —  
SPECIFICATION

ICS 11.040.30

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**BUREAU OF INDIAN STANDARDS**  
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NEW DELHI 110002

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**Price Group 2**

## FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Veterinary Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

In the preparation of this standard, assistance has been derived from British Standard 6155 : 1990 'Tracheal tubes for large animals in veterinary anaesthesia'.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## *Indian Standard*

# TRACHEAL TUBES FOR LARGE ANIMALS USED FOR VETERINARY ANAESTHESIA — SPECIFICATION

## 1 SCOPE

**1.1** This standard specifies requirements for cuffed oral tracheal tubes intended for use with large animals in veterinary anaesthesia.

## 2 REFERENCES

**2.1** The following standards contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

| <i>IS No.</i>         | <i>Title</i>                                                                                                                                             |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3234 (Part 1) : 1986  | Conical fittings with a 6 percent (LUER) taper for syringes, needles and other medical equipment: Part 1 General requirements ( <i>second revision</i> ) |
| 12504 (Part 1) : 1988 | Tracheal tubes: Part 1 General requirements                                                                                                              |
| 12504 (Part 5) : 1988 | Tracheal tubes: Part 5 Requirements and methods of test for cuffs and tubes                                                                              |
| 12572 (Part 5) : 1988 | Guide for evaluation of medical devices for biological hazards: Part 5 Method of test for intracutaneous reactivity of extracts from medical devices     |

## 3 DEFINITIONS

For the purpose of this standard, the following definitions shall apply.

### 3.1 Tracheal (Endotracheal) Tube

Tube intended for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea.

### 3.2 Patient End

That end of the tracheal tube which is intended to be inserted into the trachea.

### 3.3 Machine End

That end of the tracheal tube which is intended to protect from the patient.

### 3.4 Bavel

Standard portion at the patient end of the tracheal tube.

### 3.5 Angle of Bavel

Acute angle between the plane of the bevel and the longitudinal axis of the tracheal tube at the patient end.

### 3.6 Cuff

Inflatable sleeve fitted near the patient end of the tracheal tube to provide an effective fit between the tube and the trachea.

### 3.7 Bonded Cuff

Cuff permanently attached to the tracheal tube.

### 3.8 Inflating Tube

Tube through which the cuff is inflated.

### 3.9 Pilot Balloon

Ballon fitted to the inflating tube to indicate inflation of the cuff.

### 3.10 Large Animal

Any animal that requires the use of tubes larger than those specified in IS 12504 (Part 1) : 1988, and including the larger breeds of dogs, such as Greyhound, Alsatian and Great Dane.

## 4 MATERIAL

**4.1** The materials of the tracheal tube, including the cuff shall be assessed as being free from biological hazard when tested in accordance with IS 12572 (Part 5) : 1988. Recommendations for material and design are given in Annex A.

## 5 SIZE DESIGNATION

**5.1** The sizes of tracheal tubes shall be designated by their nominal inside diameter expressed in millimetres.

## 6 DIMENSIONS

**6.1** The dimensions of tracheal tubes shall be as given in Table 1.

6.2 The outside diameter of tracheal tubes shall be within 5 percent of the nominal value marked either on the tube [see 11.1.1(c)] or on the package [see 11.2.1(d)].

7 BEVEL

7.1 Tracheal tubes shall have a bevel with the opening to the left when the tube is viewed from the machine end towards the concave aspect, bevel end upmost.

The angle of the bevel shall be  $45 \pm 7^\circ$ .

8 CUFF

8.1 The inflatable length of the cuff and its distance from the patient end of the tracheal tube shall be as given in Table 1.

9 INFLATING TUBES

9.1 General

9.1.1 The inflating tube shall have an outside diameter not exceeding 4.5 mm and shall be situated on the concave side of the tracheal tube. The inflating tube shall not encroach on the lumen of the tracheal tube.

9.1.2 The dimensions of the inflating tube shall be such that dimension  $S_1$  (see Fig. 1) shall be  $75^{+15}_{-10}$  percent of the length of the tracheal tube and the sum of  $S_1$  and  $S_2$  shall be not less than the length of the tube.

9.1.3 If the inflating tube is attached externally to the tracheal tube between the cuff and the point of separation (see Fig. 1), the attachment shall be such that the inflating tube can be partly stripped from the tracheal tube, if required.

Table 1 Dimensions of Tracheal Tubes for Veterinary Use  
(Clauses 6.1 and 8.1)

All dimensions in millimetres.

| Designated Size (Nominal Inside Dia) | Inside Dia   | Minimum Length of Tube $L$ | Inflatable Length of Cuff $C$ | Distance of Cuff from the Patient End $B$ | Radius of Curvature |
|--------------------------------------|--------------|----------------------------|-------------------------------|-------------------------------------------|---------------------|
| (1)                                  | (2)          | (3)                        | (4)                           | (5)                                       | (6)                 |
| 35                                   | $35 \pm 1$   | 1 045                      | $200 \pm 20$                  | $60 \pm 21$                               | $500 \pm 100$       |
| 30                                   | $30 \pm 0.8$ | 1 045                      | $190 \pm 19$                  | $60 \pm 21$                               | $450 \pm 100$       |
| 25                                   | $25 \pm 0.8$ | 1 045                      | $180 \pm 18$                  | $60 \pm 21$                               | $400 \pm 100$       |
| 20                                   | $20 \pm 0.6$ | 1 045                      | $160 \pm 16$                  | $60 \pm 21$                               | $400 \pm 100$       |
| 18                                   | $18 \pm 0.6$ | 1 045                      | $160 \pm 16$                  | $60 \pm 21$                               | $400 \pm 100$       |
| 16 Standard                          | $16 \pm 0.6$ | 310                        | $60 \pm 6$                    | $30 \pm 8$                                | $250 \pm 60$        |
| Long                                 | $16 \pm 0.6$ | 550                        | $60 \pm 6$                    | $30 \pm 8$                                | $250 \pm 60$        |
| 14 Standard                          | $14 \pm 0.4$ | 310                        | $60 \pm 6$                    | $25 \pm 7$                                | $250 \pm 60$        |
| Long                                 | $14 \pm 0.4$ | 550                        | $60 \pm 6$                    | $25 \pm 7$                                | $250 \pm 60$        |
| 12 Standard                          | $12 \pm 0.4$ | 310                        | $50 \pm 5$                    | $25 \pm 7$                                | $250 \pm 60$        |
| Long                                 | $12 \pm 0.4$ | 550                        | $50 \pm 5$                    | $25 \pm 7$                                | $250 \pm 60$        |

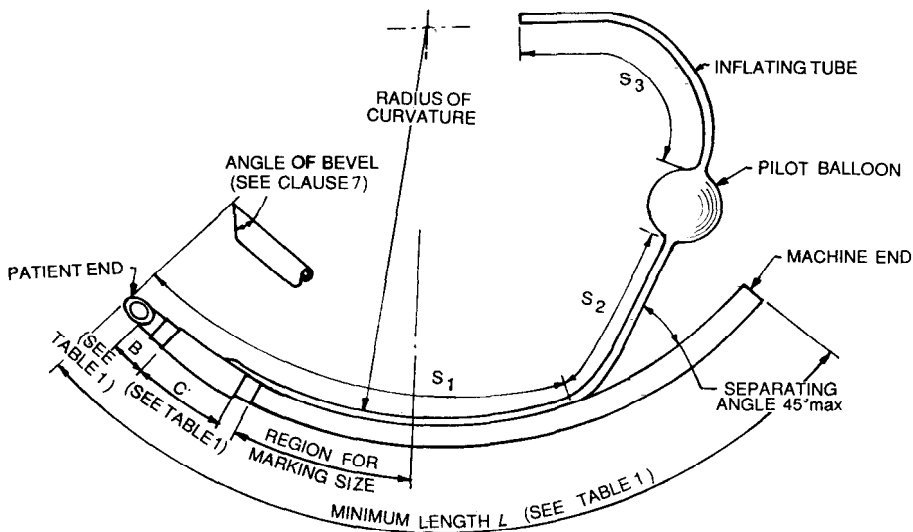


FIG. 1 TRACHEAL TUBES FOR LARGE ANIMALS IN VETERINARY ANAESTHESIA

**9.1.4** The inflating tube shall be attached to the tracheal tube such that the angle between the inflating tube and the machine end of the tracheal tube at the point of separation (*see* Fig. 1) shall not exceed  $245^{\circ}$ .

NOTE — The inflating tube should join the tracheal tube in such a way to ensure that any projection will not interfere with clinic use of the tube.

## 9.2 Pilot Balloon

The inflating tube shall be provided with a pilot balloon (*see* Fig. 1). The pilot balloon shall be so constructed as to give an indication of the inflation of the cuff and shall not prevent evacuation of the cuff.

## 9.3 Free End of the Inflating Tube

The free end of the inflating tube shall either be open or be fitted with a closure device or valve.

If the end is open, either it shall accept a male conical fitting with a 6 percent (Luer) taper complying with IS 12504 (Part 5) : 1988 or the inflating tube shall be fitted with an insert having a female conical fitting with a 6 percent (Luer) taper complying with IS 3234 (Part 1) : 1986.

Except when an inflation valve or closure device is provided, the length of the free end of the tube (dimension  $S_3$  in Fig. 1) shall be not less than 40 mm.

## 10 INFORMATION TO BE PROVIDED BY THE MANUFACTURER OR SUPPLIER

**10.1** For tracheal tubes intended for reuse, the manufacturer or supplier shall provide recommended methods of cleaning and sterilization or disinfection.

NOTE — The recommended method(s) should not product changes in the tube material which will give rise to a biological hazard (*see* 4).

## 11 MARKING

### 11.1 Marking of Tracheal Tubes

**11.1.1** Tracheal tubes intended for reuse shall be permanently and legibly marked with at least the following:

- The name and/or trade-mark of the manufacturer or supplier,
- The designated size of the tube (*see* 5),
- The nominal outside diameter of the tube expressed in millimetres,
- A means of identifying the date of manufacture, and
- The number and year of this standard.

NOTE — The marking should resist removal by anaesthetic agents and by the methods of cleaning and disinfection of sterilization recommended by the manufacturer.

**11.1.2** The marking shall be situated on the bevelled side of the tube as shown in Fig.1 and shall read from the patient end to the machine end of the tube.

NOTE — This will permit the machine end of the tube to be shortened if required without interfering with the marking.

### 11.2 Marking of Packages

**11.2.1** Packages containing tracheal tubes intended for single use shall be clearly marked with the following:

- A description of the contents,
- The name and/or trade-mark of the manufacturer or supplier,
- The designated size of the tube (*see* 5),
- The nominal outside diameter of the tube expressed in millimetres,
- A means of identifying the date of manufacturer, and
- The number and year of this standard.

## ANNEX A

(Clause 4.1)

### RECOMMENDATIONS FOR MATERIALS AND DESIGN

**A-1** Tracheal tubes should be resistant to deterioration resulting from use with anaesthetic vapours and gases.

**A-2** The tube material should have sufficient rigidity to allow the construction of tubes with the thinnest possible wall which at the same time maintain a degree of resistance to kinking. When not in use, the specified radius of curvature of the tube should be approximately maintained. When in place it should be flexible and soft enough to conform to the anatomy of the animal without exerting undue pressure on the body tissues.

**A-3** Tracheal tubes should be readily detectable by X-ray providing a suitable marker at the patient end of the tube.

**A-4** The end of the tube at the bevel should be rounded and the orifice should be free from sharp edges.

**A-5** A permanently bonded cuff should be capable of approximately symmetrical expansion when the cuff is inflated with air.

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This Indian Standard has been developed from Doc : No. MHD 17 (2328).

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